



## About SML Genetree

SML Genetree is a leading developer of multiplex molecular technologies and multiplex clinical molecular diagnostics based in South Korea. SML Genetree is recognized as a premier partner in developing technology and on-time delivery, providing both basic research in molecular biology and applied research in molecular diagnosis. SML Genetree has succeeded in commercializing the Ezplex HPV NGS Kit, gaining global recognition.

In 2020, SML Genetree developed Ezplex COVID-19 RT PCR test kits and founded SML Genetree Sciences to expand into the US market. SML Genetree was one of the first companies with a COVID-19 test to obtain emergency use approval from the South Korean Ministry of Food and Drug Safety (MFDS).

## About SML

SML Genetree is an affiliate of Samkwang Medical Laboratories (SML), one of the largest diagnostic commercial labs in South Korea since 1985. SML has continued to provide diagnostic results to customers across 3,000 government medical institutions in South Korea, including the Military Manpower Administration (MMA), university hospitals, and local medical institutions. In 2020, SML conducted approximately 3 million clinical trial tests for COVID-19. Meditree and Labtree, affiliates of SML, also support SML Genetree through related projects, such as Central Lab Service/CRO and vaccine R&D.

## Our Vision & Mission

SML Genetree strives to be a leader in the industry through continuous challenge, innovation and customer value. SML Genetree has world-class genome research competence and abundant experience leading to research and customer value. It is considered as one of the top molecular diagnostic companies in South Korea through efficiency and a value-based business system establishment and performance in the global market. SML Genetree seeks to develop a new driving force in the bio-industry by taking on the role of a pioneer in preventive and precision medicine.

### Core Capabilities

**NGS**  
(Next Generation Sequencing Analysis)

**Sequencing**

**Real-time PCR**

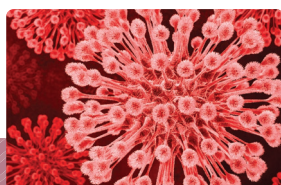
**PCR**

### Key Products

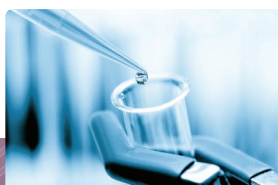
- COVID-19, including VOC kit
- Respiratory pathogen diagnostic kits (up to 19 respiratory viruses and 6 types of pneumonia-causing bacteria, including SARS-CoV-2 (COVID-19)/Flu A/Flu B/RSV diagnostic kit)
- Sexually Transmitted Infections diagnostic kits
- Tuberculosis & Non-TB diagnostic kit
- *H. pylori* and resistance diagnostic kit
- HPV genotyping diagnostic kits (NGS)
- HLA diagnostic kits for organ transplant (NGS)
- Other viral infections: HBV, HCV, HIV, SFTS



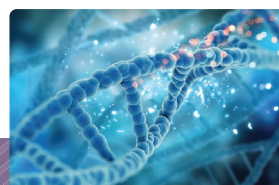
Bacterial disease



Viral disease



Drug resistance



Precision medicine for cancer



Human leukocyte antigen (HLA) typing

# Genetree History

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- 2021**
    - US FDA Emergency Use Authorization (EUA) for Ezplex SARS-CoV-2 G Kit
    - Ministry of Food and Drug Safety (MFDS) approval for Ezplex<sup>®</sup> SARS-CoV-2 Kit<sup>1</sup>
    - MFDS approval for Ezplex<sup>®</sup> SARS-CoV2/RV Fast Kit<sup>2</sup>
    - CE Authentication for Ezplex<sup>®</sup> SARS-CoV2/RV Fast G Kit<sup>2</sup>
    - CE Authentication for Ezplex<sup>®</sup> HPV NGS Typing, HP-CLA Real-time PC and MTBC/NTM Real-time PCR Kits<sup>2</sup>
    - Development of Ezplex<sup>®</sup> SARS-CoV-2 VOC Real-time PCR Kit<sup>2,3</sup>
  - 2020**
    - Expansion of sales to international markets
    - Registered by US FDA as a commercial manufacturer with intent to distribute Ezplex SARS-CoV-2 G Kit in the US
    - EUA application with a pooling claim submitted to the FDA for Emergency Use Authorization
    - CE Authentication for Ezplex<sup>®</sup> SARS-CoV-2 G Kit<sup>2</sup>
    - CE Authentication for Ezplex<sup>®</sup> SARS-CoV-2 FAST G Kit<sup>2</sup>
    - MFDS EUA approval for Ezplex<sup>®</sup> SARS-CoV-2 FAST Kit<sup>2</sup>
    - Establishment of SML Genetree Sciences, Inc., US subsidiary
    - CE Authentication for Ezplex<sup>®</sup> Respiratory Pathogen Real-time PCR Kit<sup>2</sup>
    - MFDS approval for Ezplex<sup>®</sup> Viral Respiratory, Bacterial Pneumonia and SFTS Real-time PCR Kits<sup>2</sup>
    - Company name changed to SML Genetree Co. Ltd.
    - Establishment and Korea Good Manufacturing Practice (KGMP) plus ISO 13485 of new production facility
  - 2019**
    - MFDS approval for Ezplex<sup>®</sup> HP-CLA Real-time PCR Kit<sup>2</sup>
    - MFDS approval for Ezplex<sup>®</sup> HLA-A, B, DRB1 NGS typing Kits<sup>2</sup>
    - MFDS approval for Ezplex<sup>®</sup> STD 6 and STD 7 PCR Kit<sup>2</sup>
  - 2018**
    - MFDS approval for Ezplex<sup>®</sup> HPV NGS Typing Kit<sup>2</sup>
    - MFDS approval for Ezplex<sup>®</sup> STD 12 Real-time PCR Kit<sup>2</sup>
    - MFDS approval for Ezplex<sup>®</sup> STD 13 PCR Kit<sup>2</sup>
  - 2017**
    - MFDS approval for Ezplex<sup>™</sup> MTBC/NTM Real-time PCR Kit<sup>2</sup>
    - MFDS approval for Ezplex<sup>™</sup> HLA-B\*51 Real-time PCR Kit<sup>2</sup>
    - MFDS approval for Ezplex<sup>™</sup> HLA-B\*27 Real-time PCR Kit<sup>2</sup>
    - Establishment of R&D Center
    - Sales direct to customers
  - 2016**
    - MOU of HLA Technology transfer with Korea Marrow Donor Program of Catholic University
    - Certification as a genetic testing institute.
    - ISO9001 Certification
  - 2015**
    - Completion of *in vitro* diagnostic device manufacturing site
    - KGMP Certification
    - Establishment of Genetree Research Corporation

[www.smlgenetree.com](http://www.smlgenetree.com)

For more information, contact [info@smlgenetree.com](mailto:info@smlgenetree.com)

1) MFDS: Ministry of Food and Drug Safety, formerly KFDA, Korea Food and Drug Administration

2) Not for sale in the U.S.

3) Research Use Only